

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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| In re Application of: | O'Brien |
| Application No.: | 10/725178 |
| Filed: | December 1, 2003 |
| For: | Cutting Balloon Having Sheathed Incising Elements |
| Examiner: | Diane D. Yabut |
| Group Art Unit: | 3734 |

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Alexandria, VA 22313-1450

Docket No.: S63.2-13172-US01

APPEAL BRIEF

This is an Appeal Brief for the above-identified application in which claims 1-5 and 8-14 were finally rejected, claims 6-7 were allowed and objected to and claims 15-24 were allowed in a Final Office Action mailed October 2, 2007. Currently, claims 1-24 are pending in the application.

A Notice of Appeal was filed in this case on February 4, 2008. The fees required under §1.17(c) for filing this brief were addressed in the Notice of Appeal. The Commissioner is authorized to charge Deposit Account No. 22-0350 for any other fees which may be due with this Appeal.

A copy of the claims on appeal is presented in the **Claims Appendix** below.

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(C) Real Party in Interest

The Application is assigned to Boston Scientific Scimed, Inc., formerly known as Scimed Life Systems, Inc., One SciMed Place, Maple Grove, Minnesota 55311-1566, a Minnesota corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, a Delaware Corporation.

(D) Related Appeals and Interferences

At present there are no related appeals or interferences.

(E) Status of Claims

Claims 1-5 and 8-14 were finally rejected and the subject of this appeal.

Claims 6-7 are allowed but are dependent upon a rejected base claim. Because Applicants believe that claims 6-7 are allowable in their current form, they are also the subject of this appeal.

Claims 15-24 are allowed.

(F) Status of Amendments

No amendments were submitted after the Final Office Action.

(G) Summary of Claimed Subject Matter

A summary of representative claims and a non-limiting listing of locations where support may be found [bracketed citations] is provided as follows:

Independent claim 1 recites a cutting balloon for use on a medical catheter to incise tissue at a treatment site in a body vessel of a patient [page 2, lines 22-24, page 5, lines 2-4]. The cutting balloon comprises an elongated balloon defining a longitudinal axis [page 2, lines 24-25; page 5, lines 13-15]. The balloon is inflatable from a first deflated configuration to a second radially expanded configuration [page 2, lines 24-27]. The cutting balloon also comprises an elongated incising element mounted on the balloon and oriented longitudinally [page 3, lines 1-4; page 5, lines 24-28]. The incising element has a length and extends radially from the balloon to an operative surface feature capable of incising tissue [page 3, lines 4-7; page 6, lines 3-6]. And the cutting balloon comprises a radially compressible sheath that is mounted on the balloon along the length of the incising element [page 3, lines 12-13; page 6, line 8, 20-23; Fig. 2]. The sheath extends radially from the balloon and beyond the surface feature when the balloon is in the first configuration to protect the surface feature during transit to the treatment site [page 3, line 21; page 6 line 20; page 7, lines 3-6; Figs. 3, 5, 7, and 9]. The sheath is positioned for radial compression between the tissue and the balloon to expose the surface feature for tissue incision when the balloon is inflated into the second configuration [page 3, lines 24-32; page 7, lines 7-13; Figs. 4, 6, 8, and 10].

Dependent claim 4, which depends upon dependent claim 2, which depends upon independent claim 1 recites the cutting balloon as recited in claim 1 further comprising a mounting pad for attaching the incising element to the balloon wherein the sheath is attached to the mounting pad [page 3, lines 7-9 and 17; page 6, lines 10-15].

Dependent claim 5 recites the cutting balloon as recited in claim 1 wherein the sheath comprises a pair of sheath members positioned on the balloon to interpose the incising element between the sheath members [page 3, lines 16-19; page 7, lines 14-28; page 8, lines 10-20; and Figs. 3-6, 9-10].

Dependent claim 9, which depends upon dependent claim 8, which depends upon independent claim 1 recites the cutting balloon as recited in claim 1 wherein said incising element is a blade and said surface feature is a cutting edge [page 3, lines 1-2; page 5, lines 24-26 and Figs. 3, 5 and 7]. The blade is partially encapsulated in a mounting pad and the mounting pad is bonded to the balloon [page 3, lines 9-11; page 5, line 30 to page 6, line 3 and Figs. 3-10]. Each sheath member has an azimuthal width w , and the blade has an azimuthal width, W , where the blade extends from the mounting pad, with $w > 2W$ [page 6, lines 27-30 and Fig. 3].

(H) Grounds of Rejection to be Reviewed on Appeal

1. Whether the Examiner erred in rejecting claims 1, 2, 8 and 10 under 35 USC 102(b) as being anticipated by U.S. 5,616,149 to Barath.
2. Whether the Examiner erred in rejecting claims 11-14 under 35 USC 103(a) as being unpatentable over U.S. 5,616,149 to Barath.
3. Whether the Examiner erred in rejecting claims 3-4 under 35 USC 103(a) as being unpatentable over U.S. 5,616,149 to Barath in view of U.S. 5,320,634 to Vigil.
4. Whether the Examiner erred in rejecting claim 5 under 35 USC 103(a) as being unpatentable over U.S. 5,616,149 to Barath in view of U.S. 6,730,105 to Shiber.
5. Whether the Examiner erred in rejecting claim 9 under 35 USC 103(a) as being unpatentable over U.S. 5,616,149 to Barath in view of U.S. 6,730,105 to Shiber and U.S. 5,320,634 to Vigil.

(I) Argument

The Examiner asserted that the argument against the obviousness rejection of claim 5 in the Communication to the Final Office Action argued Shiber individually and not the combination of Barath and Shiber. This assertion was wrong as Applicants did argue the combination of Barath *and* Shiber in the second paragraph of the argument against the rejection of claim 5. Therefore, in each argument presented in this Appeal Brief, the name of the reference(s) addressed in Applicants' argument will be emphasized by bold italics so that it will be obvious that the cited reference(s), alone or in combination, are being addressed in the argument.

1. **The Examiner Erred in Rejecting Claims 1, 2, 8 and 10 Under 35 U.S.C. §102(b) as Being Unpatentable over U.S. 5,616,149 to Barath.**

Independent claim 1 recites, in part, "a radially compressible sheath ... being positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision when said balloon is inflated into the second configuration" (emphasis added).

Applicants assert that *Barath* does not teach or suggest that the sheath is *radially compressed to expose the surface feature* for tissue incision, as recited in instant independent claim 1. Instead, *Barath* teaches that *inflation of the balloon* 2 exposes the cutting edges 6, not radial compression of the sheath 17. *Barath* teaches a protective sheath 17 that has a plurality of longitudinal grooves 18 covering the balloon 2.¹ When the balloon 2 is in a deflated state the longitudinal groove 18 is very small, i.e. the distance separating the two edges of the sheath 17 is small. In contrast, when the balloon 2 is in an inflated state the longitudinal groove 18 is large since the distance separating the two edges of the sheath 17 is large. Thus, in *Barath*, the cutting edges 6 are *exposed by the inflation of the balloon* 2 because inflation of the balloon 2 increases

¹ *Barath* states that "a protective sheath 17 covers the entire balloon. Continuity of the sheath is interrupted by longitudinal grooves (18)" (col. 5, lines 22 and 25-26).

the size of the longitudinal grooves 18.² This is illustrated in annotated Figs. 12 and 13 of *Barath*, provided below.

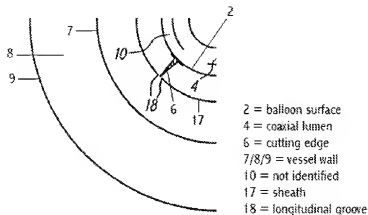


Fig. 12 of Barath Annotated
balloon is deflated and longitudinal
groove 18 is small/narrow

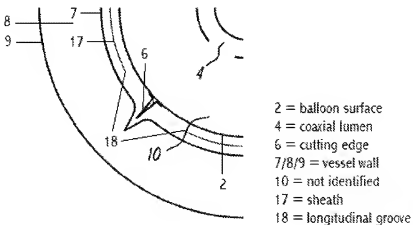


Fig. 13 of Barath. Annotated
balloon is in an inflated state
and inflation of the balloon
exposes the cutting edge 6

² *Barath* states that "[t]he grooves 18 of the protective sheath 17 open up allowing the cutting edges 6 to penetrate into the vessel wall 7,8 producing cuts with sharp margins 11. After deflation, the cutting edges retract behind the protective sheath" (col. 5, lines 30-36).

When Figs. 12 and 13 of *Barath* are compared, it is clear that, as described in the written description of *Barath*, when the balloon 2 is inflated, the longitudinal distance between the two edges of the sheath 17 increases, i.e. the longitudinal groove 18 “opens up.” As the size of each longitudinal groove 18 gets larger/wider as the balloon 2 is inflated, each cutting edge 6 is exposed so that it can “penetrate into the vessel wall 7,8 producing cuts with sharp margins 11” (col. 5, lines 30-34). Thus, *inflation of the balloon 2* causes the size of the longitudinal groove 18 to change from a narrow groove to a wide groove and *inflation of the balloon 2* exposes the cutting edges 6. In *Barath*, the sheath 17 is not being compressed between the balloon 2 and the vessel wall 7,8,9 to expose the cutting edges 6 for tissue incision when the balloon 2 is inflated, contrary to independent claim 1.

Also shown in Figs. 12 and 13 of *Barath*, the distance separating the balloon surface 2 and the sheath 17 decreases when the balloon 2 is in an inflated state as compared to a deflated state (compare Fig. 12 to Fig. 13). As shown in Fig. 13 of *Barath*, when the cutting edges 6 are making cuts with sharp margins into the vessel wall 7,8,9, the sheath 17 is separated from the vessel wall 7,8,9 by a distance and is separated from the balloon surface 2 by a distance. Therefore, the Examiner’s assertion that in Fig. 13 the cutting edges 6 are “very close to the vessel wall” and not engaging the vessel wall is wrong.³

Thus, in *Barath*, the inflation of the balloon 2, not radial compression of the sheath 17 against the vessel wall 7,8,9, causes the longitudinal grooves 18 in the sheath 17 to widen and retreat from the tip of the cutting edge 6, thereby exposing the cutting edge 6. Contrary to Examiner’s assertion, *Barath* does not state that compression of the sheath 17 against the vessel wall exposes the cutting edge 6. Therefore, *Barath* does not teach or suggest “a radially compressible sheath ... being positioned for *radial compression between said tissue and said balloon to expose said surface feature for tissue incision* when said balloon is inflated into the second configuration,” as recited in the instant claims.

³ In the Advisory Action, the Examiner stated:

When the incising elements 6 engage the vessel wall for incision (a progression from Figures 13, which shows the incising elements very close to the vessel wall 7) due to further inflation of the balloon 2, the sheath is radially compressed between the balloon and the vessel wall, and therefore is considered to be radially compressed while exposing the incising elements.

Furthermore, Applicants note that claim 1 recites “radial compression ... *to expose*.” In contrast, Examiner asserts that the sheath “is considered to be radially compressed *while exposing* the incising elements” (see Advisory Action). Applicants submit that this is in error. As discussed above, contrary to Examiner’s assertion further inflation is not necessary for the cutting edges 6 to engage the vessel wall 7,8,9 for incision. Even if further inflation were necessary, as discussed above, it does not cause the sheath 17 *to expose* the cutting edges 6, as recited in independent claim 1.

For at least this reason, Applicants request reversal of the rejection and allowance of claims 1, 2, 8, and 10.

2. The Examiner Erred in Rejecting Claims 11-14 Under 35 U.S.C. §103(a) as Being Unpatentable Over U.S. 5,616,149 to Barath.

As discussed above, *Barath* does not teach or suggest all the elements of independent claim 1, from which claims 11-14 depend. Therefore, *Barath* does not render dependent claims 11-14 obvious.

For at least this reason, Applicants request reversal of the rejection and allowance of claims 11-14.

3. The Examiner Erred in Rejecting Claims 3-4 Under 35 U.S.C. §103(a) as Being Unpatentable Over U.S. 5,616,149 to Barath In View of U.S. 5,320,634 to Vigil.

Dependent Claim 3

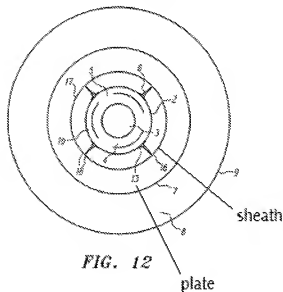
As discussed above, *Barath* does not teach or suggest all the elements of independent claim 1, from which claim 3 depends. The addition of *Vigil*, which is asserted to teach an incising element being partially encapsulated in said mounting pad, does nothing to address the failure of *Barath* to teach or suggest all the elements of the instant claim. Therefore the combination of *Barath* and *Vigil* does not render claim 3 obvious.

Dependent Claim 4

Dependent claim 4 recites “[t]he cutting balloon as recited in claim 1 further comprising a mounting pad for attaching said incising element to said balloon ... wherein said sheath is attached to said mounting pad. In the Final Office Action, the Examiner asserted that “Barath discloses the sheath 17 being attached to said mounting pad 13 (Figures 12-13).”

Applicants submit that this assertion is wrong.

In addition to failing to teach all the elements of independent claim 1, Applicants submit that *Barath* does not disclose that the sheath 17 is attached to the mounting pad 13, as recited in claim 4. Applicants note that *Barath* does not disclose that the sheath 17 is attached to the mounting pad 13 in either the written description or in Figs. 12-13. For reference, Applicants have provided an annotated copy of Fig. 12 of *Barath*:



As can be seen above, the plate 13 is mounted onto the surface of the balloon 2 and the sheath 17 is disposed about the balloon 2 with the sheath 17 being a distance away from the surface of the balloon 2 and the plate 13 (see col. 4, lines 59-65 and col. 5, lines 20-36). Therefore Applicants submit that *Barath* does not disclose a sheath engaged to the mounting pad, as recited in dependent claim 4. The addition of *Vigil*, which is asserted to disclose an incising element partially encapsulated in the mounting pad, does nothing to address the failure

of *Barath* to teach all the elements of dependent claim 4. Therefore the combination of *Barath* and *Vigil* does not render claim 4 obvious.

Conclusion

For at least these reasons, Applicants request reversal of the rejection and allowance of claims 3-4.

4. The Examiner Erred in Rejecting Claim 5 Under 35 U.S.C. §103(a) as Being Unpatentable Over U.S. 5,616,149 to Barath In View of U.S. 6,730,105 to Shiber.

Dependent claim 5 recites “wherein said sheath comprises a pair of sheath members positioned on said balloon to interpose said incising element between said sheath members.”

As discussed above, *Barath* does not teach or suggest all the elements of independent claim 1, from which claim 5 depends. The addition of *Shiber*, which is asserted to teach a sheath having a pair of sheath members, does nothing to address the failure of *Barath* to teach or suggest all the elements of the instant claim.

In the Advisory Action, the Examiner states that “Shiber is meant to be combined with the device of Barath in the rejection of claim 5.” In the response to the Final Office Action, Applicants treated the rejection as the combination of *Barath* and *Shiber*. In addition, however, Applicants objected to Examiner’s characterization of *Shiber* that was used to support the conclusion that the combination of *Barath* and *Shiber* rendered claim 5 obvious. Because claim 5 depends upon claim 1, Applicants submit that the interpretation of claim 5 is based upon both claims. Thus, for example, the pair of sheath members, recited in claim 5, is radially compressible, as recited in claim 1.

As mentioned above, Applicants object to several characterizations made about *Shiber* that were used to support the conclusion that the combination of *Barath* and *Shiber* rendered claim 5 obvious. First, Applicants object to Examiner’s assertion that the shield 77 of

Shiber is a balloon as recited in the instant claim.⁴ Second, Applicants object to the Examiner's assertion that the arch 53 and mid section 55 of Shiber are mounted on the shield 77 (*id.*).⁵

Applicants also disagree with Examiner's assertion that the arch 53 and mid section 55 of Shiber are a pair of sheath members as recited in the instant claim.⁶

Independent claim 1 recites in part "a radially compressible sheath ... being positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision when said balloon is inflated." Dependent claim 5 recites in part "said sheath comprises a pair of sheath members positioned on said balloon to interpose said incising element between said sheath members."⁷

Applicants submit that even if the halves 53/55 of *Shiber* are a pair of sheath members as recited in the instant claim, the halves 53/55 are not "positioned for radial compression ... to expose said surface feature for tissue incision when the balloon is inflated into the second configuration" as recited in independent claim 1.

Shiber states that "[a]s the expandable tube [15] is inflated and expanded the parting edge [54] moves out of the arch [53] (note FIG. 20) to part the surrounding obstruction" (col. 6, lines 19-21). Thus, *inflation of the expandable tube 15 exposes the parting edge 54, not* compression of the halves 53/55 between the shield 77, aka "balloon" and the tissue. For

⁴ "Examiner asserts that the halves of 53 or 55 seen in Figure 18 read on a pair of sheath members on either side of the incising element being mounted on a *balloon* 77" (Response to Arguments section of the Final Office Action, emphasis added).

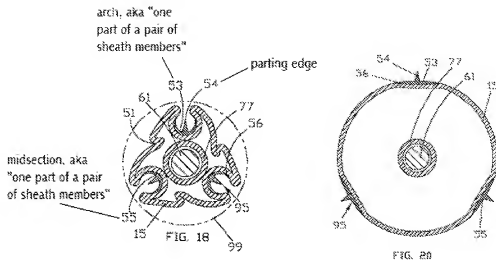
Applicant submits that *Shiber* does not teach or suggest that the shield 77 is inflatable. *Shiber* teaches that "the guidewire 61 can be disposed in a shield 77 that isolates the guidewire from the fluid that flows in conduit 69, as shown in FIG. 13 and in the fourth and fifth embodiments shown in FIGS. 14 to 21" (col. 5, lines 33-47). Thus, the shield of *Shiber* is not a balloon as recited in the instant claim.

⁵ Applicant submits that *Shiber* does not teach or suggest that the arch 53 and mid section 55 are mounted on the shield 77. *Shiber* states that the embodiment shown in Fig. 18 "utilizes ridges 95 comprising an arch 53 that is *bonded to the expandable tube 15*" and that "the mid section of the arch 55 is thicker ... to better support the parting edge 54" (col. 6, lines 8-12 and 23-24, emphasis added). Thus, neither the halves 53/55 nor the parting edge 54 are mounted on the shield 77 as asserted by the Examiner. This can be clearly seen in Fig. 20 of *Shiber*.

⁶ "Shiber teaches a sheath (upper surface of element 15) having a pair of sheath members (on either side of cutting blade 54) being positioned on said balloon to interpose said incising element 54 between said sheath members (Figure 18; col. 6, lines 8-21))

⁷ As discussed above, the interpretation of claim 5 is not conducted without reference to claim 1. Thus, the pair of sheath members, as recited in claim 5, is positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision when said balloon is inflated, as recited in claim 1.

reference, Applicants have provided Figs. 18 and 20 of *Shiber* below which show the transition from a deflated state (Fig. 18) to an inflated state (Fig. 20).



As shown above, inflation of the expandable tube 15 changes the configuration of the tube 15 from a “clover leaf” configuration to a round shaped configuration and this change in configuration due to inflation exposes the parting edges 54.

In addition, *Shiber* states that the ridges “have *a rigid cross section* to enable them to be pushed and to penetrate into the surrounding obstruction material” (col. 4, lines 54-59, emphasis added). In the embodiment shown in Fig. 18 of *Shiber*, the ridges 95 comprise an arch 53 that has a mid-section 55 and ends 56 (col. 6, lines 11 and 22-23). Applicants submit that a ridge 95, comprising an arch 53 and a mid section 55, that has a rigid cross section is not “compressible” as recited in the instant claim.

Based at least on the above, Applicants submit that *Shiber* does not teach or suggest “*a radially compressible sheath* ... being positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision when said balloon is inflated” where the radially compressible sheath “comprises a pair of sheath members” as recited in the instant claim. Because the halves 53/55 are not radially compressed to exposed said surface feature, and because the halves 53/55 are rigid and not radially compressible, *Shiber* does not teach or suggest “a pair of sheath members” as claimed, or as asserted by the Examiner.

Applicants submit that the combination of **Barath** and **Shiber** does not teach or suggest all the elements of the instant claim because **Barath** does not teach or suggest all the elements of independent claim 1 and **Shiber** does not teach or suggest all the elements of dependent claim 5 and so, in combination, **Barath** and **Shiber** do not teach or suggest all the elements of claim 5.

In conclusion, **Barath** does not teach or suggest all the elements of independent claim 1, from which claim 5 depends. The Examiner mis-characterized several features of **Shiber**. **Shiber** does not teach or suggest a sheath having a pair of sheath members as recited in the instant claim. Therefore, the combination of **Barath** and **Shiber** does not teach or suggest all the elements of instant claim 5. Applicants request reversal of the rejection and allowance of claim 5.

5. The Examiner Erred in Rejecting Claim 9 Under 35 U.S.C. §103(a) as Being Unpatentable Over U.S. 5,616,149 to Barath In View of U.S. 6,730,105 to Shiber and U.S. 5,320,634 to Vigil.

Dependent claim 9, recites in part “each said sheath member has an azimuthal width w , and wherein said blade has an azimuthal width, W , where said blade extends from said mounting pad, with $w > 2W$.”

As discussed above, **Barath** does not teach or suggest all the elements of independent claim 1, from which claim 9 depends. **Barath** also does not teach or suggest the elements of claim 9.⁸

The Examiner asserted that “Shiber teaches a sheath member (upper surface of element 15) having an azimuthal width w , and wherein said blade 54 has an azimuthal width, W , where said blade extends from said mounting pad, with $w > 2W$ (Figure 18; col. 6, lines 8-21).”⁹ Applicants submit that this assertion about **Shiber** is in error.

Applicants note that neither the azimuthal width of element 15 nor the azimuthal width of blade 54 are discussed in col. 6, lines 8-21 of **Shiber**, provided below for reference:

⁸ “Barath does not expressly [dis]close the sheath member having an azimuthal width” (Final Office Action).

⁹ See the Final Office Action and the Advisory Action where the Examiner additionally refers to Fig. 20 of **Shiber** as providing support for the assertion.

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creates a series of short cuts in the obstruction material along which the obstructing material preferentially parts. Upon deflation the flexible arch 41 urges the expandable tube to return to its clover leaf shape. While the ridge 94 is shown with a parting edge at each of its ends, optionally, additional
5 ridges can be attached to the arch or a single ridge can be attached to an arch as illustrated in the next embodiment. FIGS. 18 to 21 show a fifth embodiment with a clover leaf shaped expandable tube 15 with pleats 51 that increase the expanded tube's diameter (note FIG. 20). This embodiment
10 utilizes ridges 95 comprising an arch 53 that is bonded to the expandable tube 15. A parting edge 54 is attached to a mid section of the ridge so that when the expandable tube and the ridge are in their relaxed position the parting edge is retracted inwardly in the arch (note FIG. 18) This shields the
15 un-inflated tube 15 and blood vessel from the parting edge and reduces the likelihood of the expandable tube or vasculature being damaged by the parting edge during introduction and advancement or withdrawal of the catheter in the vasculature. As the expandable tube is inflated and expanded
20 the parting edge moves out of the arch (note FIG. 20) to part the surrounding obstruction.

As to Figs. 18 and 20 of *Shiber* supporting the Examiner's assertion, Applicants note that *Shiber* does not state that the drawings are to scale and does not give any dimensions for the medical device and therefore are unable to support Examiner's assertion.¹⁰ For at least these reasons, *Shiber* does not teach or suggest the elements of claim 9, contrary to Examiner's assertion.

¹⁰ MPEP 2125 states:

When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value. See *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000) (The disclosure gave no indication that the drawings were drawn to scale. "[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue."). However, the description of the article pictured can be relied on, in combination with the drawings, for what they would reasonably teach one of ordinary skill in the art. In re Wright, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977) ("We disagree with the Solicitor's conclusion, reached by a comparison of the relative dimensions of appellant's and Bauer's drawing figures, that Bauer 'clearly points to the use of a chime length of roughly 1/2 to 1 inch for a whiskey barrel.' This ignores the fact that Bauer does not disclose that his drawings are to scale. ... However, we agree with the Solicitor that Bauer's teaching that whiskey losses are influenced by the distance the liquor needs to 'traverse the pores of the wood' (albeit in reference to the thickness of the barrelhead)" would have suggested the desirability of an increased chime length to one of ordinary skill in the art bent on further reducing whiskey losses." 569 F.2d at 1127, 193 USPQ at 335-36.)

The addition of *Vigil*, which is asserted to teach an incising element 31 being partially encapsulated in said mounting pad 32, does nothing to address the failure of *Barath* and *Shiber* to teach or suggest all the elements of instant claim 9. Therefore the combination of *Barath*, *Shiber* and *Vigil* does not render instant claim 9 obvious. Applicants request reversal of the rejection and allowance of claim 9.

CONCLUSION

Instant claims 1, 2, 8 and 10 are patentably distinct over Barath; claims 11-14 are patentably distinct over Barath; claims 3-4 are patentably distinct over Barath in view of Vigil; claim 5 is patentably distinct over Barath and Shiber; claim 9 is patentably distinct over Barath, Shiber and Vigil. Instant claims 6-7, which were allowed by Examiner but dependent upon a rejected base claim, are patentable in their current form. Consequently reversal of the rejections and the objection is respectfully requested.

Respectfully submitted,

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Date: March 11, 2008

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(J) Claims Appendix

1. A cutting balloon for use on a medical catheter to incise tissue at a treatment site in a body vessel of a patient, said cutting balloon comprising:

an elongated balloon defining a longitudinal axis, said balloon being inflatable from a first deflated configuration to a second radially expanded configuration;

an elongated incising element mounted on said balloon and oriented longitudinally, said incising element having a length and extending radially from said balloon to an operative surface feature capable of incising tissue; and

a radially compressible sheath mounted on said balloon along the length of said incising element and extending radially from said balloon and beyond said surface feature when said balloon is in the first configuration to protect said surface feature during transit to the treatment site, said sheath being positioned for radial compression between said tissue and said balloon to expose said surface feature for tissue incision when said balloon is inflated into the second configuration.

2. The cutting balloon as recited in claim 1 further comprising a mounting pad for attaching said incising element to said balloon.

3. The cutting balloon as recited in claim 2 wherein said incising element is partially encapsulated in said mounting pad and said mounting pad is bonded to said balloon.

4. The cutting balloon as recited in claim 2 wherein said sheath is attached to said mounting

pad.

5. The cutting balloon as recited in claim 1 wherein said sheath comprises a pair of sheath members positioned on said balloon to interpose said incising element between said sheath members.

6. The cutting balloon as recited in claim 5 wherein each said sheath member is formed as a hollow tube.

7. The cutting balloon as recited in claim 5 wherein each said sheath member extends a radial distance, d , from said balloon when uncompressed and said incising element extends a distance, D , from said balloon, with $d > D$.

8. The cutting balloon as recited in claim 1 wherein said incising element is a blade and said surface feature is a cutting edge.

9. The cutting balloon as recited in claim 8 wherein said blade is partially encapsulated in a mounting pad, said mounting pad is bonded to said balloon, each said sheath member has an azimuthal width w , and wherein said blade has an azimuthal width, W , where said blade extends from said mounting pad, with $w > 2W$.

10. The cutting balloon as recited in claim 8 wherein said cutting edge of said blade is

embedded in said sheath when said balloon is initially in said first configuration, said cutting edge oriented relative to said balloon to cut through said sheath for exposure of said cutting edge to incise tissue during radial compression of said sheath.

11. The cutting balloon as recited in claim 1 wherein said incising element is a round wire.
12. The cutting balloon as recited in claim 1 wherein said incising element is made of a hardened polymer.
13. The cutting balloon as recited in claim 1 wherein said sheath is made of a low durometer material.
14. The cutting balloon as recited in claim 1 wherein said sheath is made of a porous polyurethane material.

(K) Evidence Appendix - None

(L) Related Proceedings Appendix - None